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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,028	09/09/2003	Stanley J. Korsmeyer	20363-021	4042

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,028	KORSMEYER ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1,2,8-10 and 12-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/04, 3/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *exhibit A,B*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-7 and 11), SEQ ID NO: 4, and species BCL-2 in the reply filed on 7/29/06 is acknowledged.

Applicants argue that up to 10 independent and distinct nucleotide sequences can be examined in a single application without restriction and search of prior art relevant to the SEQ ID NO: 4 necessarily encompasses the sequence of SEQ ID NOs: 3 and 5-7.

These have been considered, but not found persuasive. Because each of SEQ ID NOs is a unique and separately patentable sequence, they require separate searches for the sequences and the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. For this reason, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made **FINAL**.

Claims 1-32 are pending. Claims 1-2, 8-10 and 12-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 3-7 and 11 extended to SEQ ID NO: 4 and species BCL-2 will be examined on the merits.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 2/19/04 and 3/1/06 is/are considered by the examiner and initialed copy/copies of the PTO-1449 is/are enclosed.

Priority

Applicants claim benefits of U.S. provisional applications 60409488, filed on 9/9/2002 and 60495036, filed on 8/14/03, which are acknowledged.

Claim Objections

The claims 3-7 and 11 are objected to as being drawn to a nonelected invention. Applicants have elected SEQ ID NO: 4, one isolated peptide, and BCL-2, for examination at this time. However the instant claims contain subject matters drawn to none-elected invention claiming SEQ ID NOs and non-

elected species. Applicants are required to re-write the claims to contain only SEQ ID NO: 4 and BCL-2 for the purpose of examination at this time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 3-5 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Fesik et al., (WO02/20568, Publication Date, 3/14/2002, effective filing date 9/6/00) as evidenced by protein search (exhibit A).

Claims 3-4 are drawn to an isolated peptide comprising amino acid sequence shown in SEQ ID NO: 4, wherein the peptide binds to BCL-2. Claim 5 is interpreted as drawn to an isolated peptide consisting of an amino acid sequence shown in SEQ ID NO: 4.

Fesik et al., disclose a peptide having amino acid sequence, which is 100% identical to the peptide of SEQ ID NO: 4 as evidenced by sequence search (exhibit A). Fesik et al., disclose that the peptide, shown in SEQ ID NO: 10, is fragment of BAD protein, which binds to BCL-2 (page 9 and 12-14).

2. Claims 3-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Horne et al., (US Patent, 5965703, Oct 12, 1999) as evidenced by sequence search (exhibit B).

Claims 3-4 are set forth above. Claim 11 is drawn a composition comprising a peptide of claims 3 and a carrier.

Horne et al., disclose a BCL-2 Associated Death (BAD) polypeptide comprising an amino acid sequence (residues at 103-127), which is 100% identical to the peptide of SEQ ID NO: 4 as evidenced by sequence search (exhibit B). The peptide disclosed by Horne et al., shown as SEQ ID NO: 2, has 168 amino acid residues and binds to the member of BCL-2 family (column 3-4, and figures 1 and 4). Horne et al., also disclose a pharmaceutical composition comprising the BAD polypeptide or BCL-2 binding domain of the BAD polypeptide and carriers for the purpose of administration to a subject (column 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquires set forth in Graham V. john Deere Co., 383 U.S. 1, 148 USPQ 459 (1996), that are applied for establishing a background for determining obviousness under 25 U.S. C. 103 (a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or obviousness

1. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fesik et al., (WO02/20568, Publication Date, 3/14/2002, effective filing date 9/6/00) or Horne et al., (US Patent,

5965703, Oct 12, 1999) in view of Matsushita et al., (J of Neuroscience, vol 21, page 6000-6007, August 15, 2001).

Claims 6-7 are drawn to a chimeric peptide comprising the peptide of SEQ ID NO: 4 and a translocation sequence, which facilitates transport across a biological membrane, wherein the translocation sequence is polyarginine.

Fesik et al., teach a peptide consisting of amino acid sequence identical to SEQ ID NO: 4 as described above.

Horne et al., teach a peptide comprising an amino acid sequence locally identical to SEQ ID NO: 4 as described above.

Fesik et al., or Horne et al., do not teach a chimeric peptide containing a translocation sequence or polyarginine.

Matsushita et al., teach that polyarginine is protein transduction domain (PTD), which is not only capable of entering a cell, but also can be used to deliver a molecule into a cell. Matsushita et al., teach a chimeric protein comprising 11 arginines (11R) fused to enhanced green fluorescence protein (EGFP, page 6000, column 2). Matsushita et al., teach that the chimeric peptide (11R-EGFP) is transported cross the membrane of cells, which is facilitated by polyarginine (page 6001, figure 1 and page 6002).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make a chimeric peptide comprising BCL-2 binding peptide comprising amino acid sequence SEQ ID NO: 4 fused with polyarginine to enhance an ability of penetrating the peptide to the cells. One of ordinary skill in the art would have been motivated to combine the teaching of Matsushita et al., with the teaching of Fesik et al., or Horne et al., to make such chimeric peptide for treating a disease involved in the abnormal expression or function of BCL-2 associated protein by increaseing an ability of penetrating the chimeric peptide into the cells. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to make such chimeric peptide because Fesik et al., have shown BCL-2 binding peptide of SEQ ID NO: 4, Horne et al., have shown the BCL-2 binding peptide comprising amino acid sequence SEQ ID NO: 4 and Matsushita et al., have shown polyarginine, which has an ability to deliver a peptide into cells and a chimeric peptide having a polyarginine.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER